REMARKS

Applicants thank SPE Page for the courtesies extended during an interview on September 2, 2005, in the instant application. The claim amendments and remarks presented herein reflect the issues discussed during that interview and summarized on the Interview Summary Record.

Applicant respectfully requests entry of the claim amendments presented above. These amendments reflect the suggestions made by SPE Page during the September 2, 2005, interview, in addition to ministerial amendments that render the claims self-consistent. Applicants respectfully submit that these amendments require no additional search and place the claims in condition for allowance, and therefore request entry of the amendments. If the amendments are entered, claim 19 will be amended, claims 1-18 and 20-22 will be canceled, and claims 23-42 will be added. The claim amendments are fully supported by the specification.

In the Official Action of May 6, 2005, claims 1-3, 6, 9, 10, 12-15 and 19 were rejected for obviousness-type double patenting over claims 1-21 of copending application Serial No. 10/324,953. Claims 1-22 were rejected under 35 USC § 103(a) as obvious over Laruelle in view of Chen. The specific grounds for rejection, and applicants' response thereto, are set forth in detail below.

Support for the claim amendments

The claims have been amended in the manner suggested by SPE Page during the September 2, 2005 interview. Method claim 19 has been amended to include the limitations of now-canceled claim 1, which was directed to a formulation. Added claims 23-42 are supported by now-canceled claims 1-18 and 2-22 respectively.

Claim rejection for obviousness-type double patenting

Claims 1-3, 6, 9, 10, 12-15 and 19 are rejected for obviousness-type double patenting over claims 1-21 of copending application Serial No. 10/324,953. However, the USPTO has

deemed application Serial No. 10/324,953 abandoned for failure to respond to an office action and therefore the rejection is moot.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1-22 are rejected under 35 USC § 103(a) as obvious over Laruelle in view of Chen. Specifically, the Examiner alleges that Laruelle discloses a formulation of fenofibrate in DGME where the weight ratio of DGME and fenofibrate falls within applicants' claimed range, and that Laruelle further discloses additives that aid in solubilization of the fenofibrate or stabilization of the formulation. The Examiner admits that Laruelle fails to disclose formulations containing surfactant or stabilizing agent, but asserts that this deficiency is remedied by Chen. The Examiner further admits that neither Laruelle nor Chen teach or suggest the amounts of ingredients recited in applicants' claims but asserts that "it is not inventive to discover the optimum or workable ranges by routine experimentation." Applicants respectfully traverse.

When combining references to make out a *prima facie* case of obviousness, the examiner is obliged to show by citation to specific evidence in the cited references that (i) there was a suggestion/motivation to make the combination and (ii) there was a reasonable expectation that the combination would succeed. Both the suggestion/motivation and reasonable expectation must be found within the prior art, and not be gleaned from applicants' disclosure. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re Dow Chemical Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988); *W.L. Gore v. Garlock, Inc.*, 220 USPQ 303, 312-13 (Fed. Cir. 1983) (holding that is improper in combining references to hold against the inventor what is taught in the inventor's application); *see also* MPEP §§ 2142-43 (August 2001). In the present case, the Examiner has failed to set forth adequate reasons as to why one of ordinary skill in the art would have been motivated to combine the cited references and therefore no *prima facie* case of obviousness exists, and the rejection should be withdrawn.

Laruelle describes compositions containing fenofibrate and DGME, but fails completely to describe methods of treatment using a composition containing *any other* defined ingredient, let

alone the ingredients specified in the instantly claimed invention. The Examiner asserts that Laruelle at column 3, lines 20-23 suggests adding additional components to increase the solubility and stability of the fenofibrate. Applicants respectfully submit, however, that the *entire* disclosure directed to solubilizers and stabilizers is the following:

> According to another advantageous embodiment of the fenofibrate solution, it additionally comprises additives capable of increasing the solubilizing power of DGME and/or of increasing the stability of the said solution.
>
> * * *
>
> Water-miscible glycol additives, as well as antioxidants, can be included in the proposed formula in order to substantially increase the solubilizing power of the DGME and to ensure the stability of the composition.

See column 3, lines 20-23 and column 4, lines 39-41 respectively. Nothing in Laruelle, however, would provide one of ordinary skill in the art with any further information regarding either the nature or amounts of these additives, let alone direct one to the use of a surfactant . This complete lack of disclosure leaves the person of ordinary skill in the art with no guidance whatsoever as to how to go about improving Laruelle's compositions using other solubilizers or stabilizers. Such a generalized statement amounts to no more than wishful thinking and fails both prongs of the two part test under *Vaeck*. First, without any guidance as to where to look for additional ingredients, Laruelle cannot motivate one of ordinary skill in the art to combine Laruelle with a secondary reference, because of the complete lack of guidance as to what type of reference to look for. Second, in the absence of any detail regarding the nature of the additional ingredients, there cannot be a reasonable expectation of success.

The Examiner admits that Laruelle fails to disclose formulations containing surfactant or stabilizing agent, but asserts that this deficiency is remedied by Chen. Nothing in Chen, however, would provide the missing motivation to modify the compositions disclosed by Laruelle, and to use the resulting compositions in the instantly claimed methods of treatment. In particular, Chen's compositions contain triglycerides as an essential and major component. By contrast, the instant claims are directed to methods of treatment using a drug such as fenofibrate

that lower serum triglyceride levels in a patient. See page 1 of applicants's specification. Accordingly, one of ordinary skill would not have been motivated to combine Laruelle and Chen to arrive at the instantly claimed methods of treatment because Chen necessarily teaches away from methods that are intended to lower serum triglyceride levels in a patient.

In sum, there would have been no motivation to combine Laruelle and Chen and, even if such a motivation existed, nothing in the combined references would have guided one of ordinary skill in the art to applicants' claimed invention, nor provided a reasonable expectation that such a combination would be successful. Accordingly, no *prima facie* case of obviousness has been made and the rejection should be withdrawn.

CONCLUSION

In view of the above amendment and remarks, applicants respectfully request that all objections and rejections be withdrawn and that a notice of allowance be forthcoming. The Examiner is invited to contact the undersigned attorney for applicants at 202-912-2197 for any reason related to the advancement of this case.

Respectfully submitted,

Date: October 20, 2005

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